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10/600,957	06/20/2003	Garth Powis	126387.530	6628

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Pepper Hamilton LLP
One Mellon Center, 50th Floor
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EXAMINER

FETTEROLF, BRANDON J

ART UNIT	PAPER NUMBER
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1642

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08/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,957	Applicant(s) POWIS, GARTH	
	Examiner BRANDON J. FETTEROLF	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-18 and 21-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-18 and 21-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

The amendment filed on 6/08/2009 in response to the Non-Final Office Action (12/08/2008) is acknowledged and has been entered.

Claims 9–18 and 21–40 are currently pending and under consideration.

Priority

After reviewing the Provisional Application, SN: 60/031995, for the disclosure of a drug comprising 2-imidazole disulfide formulated in a suitable dosage and a pharmaceutically acceptable carrier for injection or oral administration, the Examiner has established a priority date of December 5, 1997 consistent with the filing of PCT/US97/22292. If applicant disagrees with any rejection of claims 9–18 and 21–40 set forth in this office action based on examiner's establishment of a priority date of December 5, 1997 for the instant claims in application serial number 10/600,957 applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

Rejections Maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9–18 and 21–40 remain rejected under 35 U.S.C. 102(a) as being anticipated by Powis et al . (Anti-Cancer Drugs December of 1996; 7 (Suppl. 3): 121-126, IDS).

Powis et al . teach a composition comprising 1-methylpropyl-2-imidazolyl disulfide formulated for intraperitoneal injection or oral administration with a suitable amount of compound to inhibit tumor growth (page 125, Figure 5 and Table 2). With regards to the suitable amount, the

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publication teaches that a suitable amount includes, 5 mg/kg, 10 mg/kg, or 15 mg/kg, e.g., 15, 30 or 45 mg/m² (see Applicants Remarks, page 8 out of 10), for intraperitoneal injection or 250 ppm for oral administration (page 125, Figure 5 and Table 2).

In response to this rejection, Applicants assert that Powis and Kirkpatrick are co-inventors of the presently claimed subject matter. Accordingly, Applicants direct the Examiner to co-pending US Application No. 10/366,751, wherein a Declaration was submitted to the Office by both Kirkpatrick (submitted on 10/10/2005) and Powis (submitted on 3/7/2005) stating that the submitted matter claimed in such application, including particular claims to a composition comprised of a salt of 1-methylpropyl 2-imidazolyl disulfide and a pharmaceutically acceptable carrier, was solely invented by Kirkpatrick and the other co-authors listed in Powis were not inventors. Accordingly, Applicants submit that as previously established through both the declarations and the issuance of the 6,689,775 (Powis sole inventor directed to inhibiting tumor growth *in vivo*), such subject matter invented by both Kirkpatrick and Powis, and the remaining co-authors of the Powis reference are not inventors of such subject matter and were only involved with respect to such an invention as an assistant to work under the supervision of the inventors and were listed solely to receive academic credit.

These arguments have been carefully considered, but are not found persuasive.

Applicant refers to an affidavit or declaration filed in a prior filed application. Affidavits or declarations, such as those submitted under 37 CFR 1.130, 1.131, and 1.132, filed during the prosecution of the prior application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit or declaration, the applicant should make the remarks of record in this application and include a copy of the original affidavit or declaration filed in the prior application.

Claims 9–18 and 21–30 remain rejected under 35 U.S.C. 102(b) as being anticipated by Oblong et al. (Cancer Chemotherapy and Pharmacology 1994; 34: 434–438, *IDS, of record*) as evidenced by Chaplan et al. (US 5,849,737, 1998, of record) and Padmanaban (US 20070105945, 2007, of record).

Oblong et al. teach a composition comprising an agent in DMSO, wherein the agent acts as a reversible inhibitor of human thioredoxin (page 435, 1st column, *TR assay*, page 436, 1st column, 1st

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full paragraph and Title). With regards to the thioredoxin inhibitor, the reference teaches that the thioredoxin inhibitors are alkyl 2-imidazole disulfide analogues, such as 1-methylpropyl-2-imidazolyl disulfide (Title and page 435, 1st column, *Chemicals* and Fig. 1). Moreover, the reference teaches that the alkyl 2-imidazolyl disulfide analogues are useful at inhibiting cellular proliferation, e.g. cell growth (page 437, Fig. 4A,B and 2nd column, last paragraph). Thus, while Oblong et al. do not explicitly teach that the agent is useful in reducing or eliminating thioredoxin-associated apoptosis inhibition, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982). Secondly, although Oblong et al. does not explicitly teach that DMSO is an acceptable carrier for intravenous administration, the claimed limitation does not appear to result in a manipulative difference when compared to the prior arts disclosure because as evidenced by Chaplan et al., DMSO is an example of an acceptable carrier for intravenous administration (Example 1, lines 27-28). Similarly, although Oblong et al. does not explicitly teach that DMSO is an acceptable carrier for oral administration, the claimed limitation does not appear to result in a manipulative difference when compared to the prior arts disclose because as evidenced by Padmanaban et al., DMSO is an example of an acceptable carrier for oral administration (paragraph 0031). Thus the claimed composition appears to be the same as the prior art.

In response to this rejection, Applicants contend Oblong is not appropriate prior art in that Oblong does not, among other things, teach "suitable dosage amount" as recited in the claims of the instant application. Moreover, Applicants contend that Oblong fails to anticipate claims 7-30 because Oblong only teaches that the 2-imidazolyl disulfides of Oblong (including 1-methylpropyl 2-imidazolyl disulfide, also referred to as IV-2) inhibit the thioredoxin/thioredoxin reductase system (the "System"), but does not describe the inhibition of thioredoxin (as determined by Applicant). Additionally, Applicants contend that "they" are the first to disclose appropriate dosages of 2-imidazolyl disulfides, including 1-methylpropyl-2-imidazolyl disulfide, for injection and oral administration, and was the first to demonstrate the therapeutic effects of such dosages in vivo. Thus, Applicants submit that Oblong fails to anticipate claims 7-40, and this rejection should be withdrawn.

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These arguments have been carefully considered, but are not found persuasive.

Regarding Applicants assertions pertaining to Oblong et al. dosing, the Examiner acknowledges Applicants assertions that the instant claims encompass a drug comprising a 2-imidazolyl disulfide and a pharmaceutically acceptable carrier for either injection or oral administration that is formulated in a suitable dosage amount for reducing or eliminating thioredoxin-associated apoptosis inhibition or thioredoxin stimulated cell growth; and further, Oblong et al. discloses an in vitro assay. However, the Examiner recognizes that Oblong et al. teach a 10 mM solution comprising the claimed compound, e.g., 1-methylpropyl-imidazolyl disulfide, in DMSO, e.g., a pharmaceutically acceptable carrier. Thus, while the reference does not explicitly teach that a 10 mM solution is a suitable dosage amount for reducing or eliminating thioredoxin-associated apoptosis or thioredoxin stimulated cell growth, the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Thirdly, with regards to Applicants assertions that Oblong et al. teaches that the compounds inhibit the "system", the Examiner acknowledges Applicants contention that they unexpectedly found that select asymmetric disulfides behaved principally as inhibitors of thioredoxin rather than TR, thioredoxin reductase. However, the Examiner recognizes that Oblong et al. teaches a pharmaceutical composition which comprises the claimed 1-methylpropyl-imidazolyl disulfide, in DMSO; and therefore, the prior arts composition would inherently function the same as the claimed product. As such, granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-40 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Oblong et al. (Cancer Chemotherapy and Pharmacology 1994; 34: 434-438, *IDS*) as evidenced by Chaplan et al. (US 5,849,737, 1998) and) and Padmanaban (US 20070105945, 2007).

Oblong et al. teach a composition comprising an agent in DMSO, wherein the agent acts as a reversible inhibitor of human thioredoxin (page 435, 1st column, *TR assay*, page 436, 1st column, 1st full paragraph and Title). With regards to the thioredoxin inhibitor, the reference teaches that the thioredoxin inhibitors are alkyl 2-imidazole disulfide analogues, such as 1-methylpropyl-2-imidazolyl disulfide (Title and page 435, 1st column, *Chemicals* and Fig. 1). Moreover, the reference teaches that the alkyl 2-imidazolyl disulfide analogues are useful at inhibiting cellular proliferation, e.g. cell growth (page 437, Fig. 4A,B and 2nd column, last paragraph). Thus, while Oblong et al. do not explicitly teach that the agent is useful in reducing or eliminating thioredoxin-associated apoptosis inhibition, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982). Secondly, although Oblong et al. does not explicitly teach that DMSO is an acceptable carrier for intravenous administration, the claimed limitation does not appear to result in a manipulative difference when compared to the prior arts disclosure because as evidenced by Chaplan et al., DMSO is an example of an acceptable carrier for intravenous administration (Example 1, lines 27-28). Similarly, although Oblong et al. does not explicitly teach that DMSO is an acceptable carrier for oral administration, the claimed limitation does not appear to result in a manipulative difference when compared to the prior arts disclose because as evidenced by Padmanaban et al., DMSO is an example of an acceptable carrier for oral administration (paragraph 0031). Thus the claimed composition appears to be the same as the prior art.

Oblong et al. do not teach that the amount of 1-methylpropyl-2-imidazole disulfide is 15-45 mg/m² or 250 mg/kg.

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However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the dosage of 1-methylpropyl-2-imidazole disulfide as taught by Oblong et al. One would have been motivated to do so because optimization of effective amounts of known agents to be administered is considered will in the competence level of an ordinary skilled artisan in the pharmaceutical sciences, involving merely routine skill in the art. Moreover, it has been held that that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect (See *In re Boesch*, 205, USPQ).

In response to this rejection, Applicants contend that Applicants have unexpectedly found that select asymmetric disulfides behaved principally as inhibitors of thioredoxin rather than as substrates of TR. In particular, Applicants point to Table 2 of Applicant's co-pending US Application 10/366,751 which emphasizes the importance and difference between the substrate, inhibitor, and the non-reactive nature of select asymmetric disulfides. For example, Applicants contend that as shown in Table 2, a difference in only two carbon atoms within the carbon chain renders a compound a substrate of TR instead of an inhibitor of thioredoxin (III-2 of VI-2 versus IV-2). Thus, while it may have been recognized in the art that all of these compounds may be of interest because they were disulfides, Applicants contend that the discovery that structurally similar compounds behaved dramatically different is the very essence of determining the "suitable dosage amount" of the presently claimed compound. Applicants further raise the question of why would the skilled artisan choose IV-2 (an inhibitor), instead of IX-2 (a non-reactive species) or IV-2 instead of VI-2 (a substrate) without knowing their role as an inhibitor of thioredoxin, a substrate or thioredoxin reductase or a non-reactive species?

In response to these arguments, the Examiner acknowledges and appreciates Applicants pointing out the differences between some asymmetric 2-imidazole disulfides including those which are not taught by Oblong et al. Moreover, the Examiner acknowledges Applicants question as to why one of skill in the art would choose IV-2 as taught by Oblong. However, the Examiner recognizes that while any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, Oblong teaches compositions

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comprising alkyl 2-imidazolyl disulfide analogues which are useful at inhibiting cellular proliferation, e.g. cell growth (page 437, Fig. 4A,B and 2nd column, last paragraph). In particular, Oblong teaches that IV-2 was considerably more potent as an inhibitor of the thioredoxin-dependent cellular proliferation of Swiss 3T3 fibroblasts. Accordingly, Oblong provides the motivation to select IV-2 out of the other two disulfides, not the present application or Applicants copending application.

Applicants further contend that any purported *prima facie* case of obviousness has been rebutted by the establishment of unexpected properties. For example, Applicants assert that the claimed disulfide (e.g., 1-methylpropyl 2-imidazolyl disulfide) was unexpectedly an inhibitor of thioredoxin, as opposed to the teaching in the art that asymmetric disulfides (including the presently claimed disulfide) were substrates of thioredoxin reductase (TR) (not inhibitors of thioredoxin). Additionally, Applicants contend that in maintaining the rejection, the Examiner fails to appreciate the nature and importance of enzyme kinetics and provides a simplified schematic of the intermediate interaction at any time between thioredoxin (Trx) in its oxidized form and inactive form. Thus, Applicants assert that the implications of Applicant's unexpected discovery that 1-methylpropyl 2-imidazolyl disulfide as specific, irreversible inhibitors of thioredoxin is that these compounds are suitable for use as a therapeutic or pharmaceutical composition because they demonstrate (i) specificity for inhibiting thioredoxin, in contrast to the non-specificity of the other asymmetric disulfides and (ii) increased efficacy for inhibiting thioredoxin associated cellular proliferation.

In response to Applicants assertions, the Examiner acknowledges and does not dispute Applicants contention that Applicants have unexpectedly found that 1-methylpropyl 2-imidazolyl disulfide is an inhibitor of thioredoxin. However, the Examiner recognizes that mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). In the instant case, Oblong et al. teach a composition comprising 1-methylpropyl-2-imidazolyl disulfide in DMSO which is useful at inhibiting cellular proliferation, e.g. cell growth (page 437, Fig. 4A,B and 2nd column, last paragraph). Oblong et al. do not teach that the amount of 1-methylpropyl-2-imidazole disulfide is 15-45 mg/m² or 250 mg/kg. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the dosage of 1-methylpropyl-2-imidazole disulfide as taught by Oblong et al. One would have been motivated to do so because optimization of effective amounts

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of known agents to be administered is considered will in the competence level of an ordinary skilled artisan in the pharmaceutical sciences, involving merely routine skill in the art. Moreover, it has been held that that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect (See *In re Boesch*, 205, USPQ). Thus, granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

New Rejections Necessitated by Amendment:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9–18 and 21–40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 49–50, 52–60 and 63–69 of copending Application No. 10/366,751. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pharmaceutical composition claimed in the conflicting patent application appears to fall within the same scope as the drug claimed in the patent currently under examination.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Therefore, No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON J. FETTEROLF whose telephone number is (571)272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Brandon J Fetterolf

Primary Examiner

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/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642